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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/720,411
Filing Date: March 12, 2001
Appellant(s): CZERNUSZKA ET AL.

Richard T. Roche
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 6-28-05 appealing from the Office action mailed 6-29-04.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences:

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

1) EP 0 479 582: 4-1992

2) Eanes, E. D., Calcif Tissue Int vol. 40, pp. 43-48, 1987

3) Eanes E. d., Bone and Mineral, vol. 17, pp. 269-272, 1992.

4) US 5,039,546 (Chung), 8-1991

5) US 5,310,484 (Redepenning), 5-1994

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC ' 103

1. Claims 1-2, 6-12, 14-16, 21-23, 26-29 and 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 479 582 in combination with either of Eanes (Bone and Mineral, 17, pp., 269-272, 1992) or Eanes (Calcif. Tissue Int (40, pp 43-48, 1987) in further combination with Chung (5,039,546).

EP discloses multilamellar liposomes containing an antibiotic. The liposomes are suspended in hydroxy apatite (hydroxy -calcium phosphate). The compositions are useful as dental implants (note the abstract, columns 4-7 and claims). What is lacking in EP is the teaching of the coating of the liposomes with apatite (calcium phosphate) instead of hydroxy-apatite. What are also lacking in EP are the teachings of the attachment of the liposomes to a surface.

Eanes in both publications discloses liposomes coated with calcium phosphate; liposomes are made of phosphatidylcholine. The liposomes are suspended in NaCl and

therefore, the surface layer containing chloride ions as recited in claim 6 is inherent in the prior art composition (note the abstract, and Table 1 on page 270 in Bone and Mineral; summary, Materials and Methods and discussion in Calcif. Tissue Int.). What is lacking in Eanes is the explicit teaching of the thickness of the coating of the vesicles by the calcium phosphate. However, on page 270, Eanes appear to suggest that the coating on the external surface is time dependent and PL dependent and therefore, it would have been obvious to one of ordinary skill in the art to obtain the vesicles with a desired coating thickness by varying the time and the selection of suitable phospholipids.

In essence, Eanes teaches the formation of coatings of calcium phosphate on the liposomal surface when suspended in calcium phosphate solutions.

Chung discloses that for dental implants (ceramic or metal) coated with either hydroxy apatite or calcium phosphate are known and routinely used in dental and orthopedic areas (note the abstract, columns 1-2 and claims).

The use of calcium phosphate instead of hydroxy apatite in EP would have been obvious to one of ordinary skill in the art since Eanes teaches that the liposomes can be coated with calcium phosphate and Chung teaches that both hydroxy apatite and calcium phosphates are routinely used in dental implant area. Further coating the composition of EP over a substrate would have been obvious to one of ordinary skill in the art, with a reasonable expectation of success since Chung teaches that either hydroxy apatite or apatite are coated on a substrate for use in dental and orthopedic areas. Chung does not disclose specifically the sizes of the implants. However, it is

deemed to be within the skill of the art to use the desired sizes since sizes depend on the site the implant is to be used.

2. Claims 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 479 582 of record in combination with either of Eanes (Bone and Mineral) or Calcif. Tissue Int., cited above and Chung (5,039,546), further in view of Redepenning (5,310,464).

The teachings of EP, Eanes and Chung have been discussed above. Chung in particular teaches the coating of calcium phosphate on metal or ceramic implants. What is lacking in the cited prior art is that the process of coating be conducted electrolytically.

Redepenning discloses that when the metallic implants are coated by electrolytic process, the coating is superior to the coating obtained by conventional processes. Redepenning's process involves immersing the implant in a solution of calcium and dihydrogen phosphate and coating the implant by electrolysis (note the abstract, col. 3, line 38 et seq; and claims).

The use of electrolysis for the coating of liposomes containing an outer layer of calcium phosphate over a metallic implant would have been obvious to one of ordinary skill in the art because Redepenning teaches that electrolytic process is superior to the conventional processes.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant cites In re Hoeksema, 399 F. 2d 269 (CCPA 1968) and argues that in this case, the court answered the question whether a claimed compound may be

said to be legally obvious when no process of making the compound is shown in the prior art relied upon. Applicant's arguments based on In re Hoeksema are not persuasive; Hoeksema is not applicable in instant case since unlike in Hoeksema, the primary reference (EP 0 479 582) applied by the examiner clearly teaches the preparation of antibiotic containing liposomes and adding hyroxyappatite to these liposomes on page 5, line 34 through page 6, line 12. Instant process claim 16 recites " a) forming a vesicle in an aqueous mixture comprising a phospholipid and a pharmaceutically active compound and b) calcifying the outer surface of the vesicle by contacting said vesicle with an aqueous solution comprising calcium and phosphate ions". The secondary references of Eanes are added only to show the use of calcium phosphate to coat liposomes. Applicant argues that the declaration makes it clear that the process of the prior art references could not produce the invention of claim 1 and in particular, the processes of Eanes would puncture the walls of the vesicles thereby making the containment of a pharmaceutically active agent within the vesicle impossible. This argument is not found to be persuasive since there is nothing in Eanes to indicate that calcium phosphate, which is outside would make the entrapped active agent to leak out. In fact, Eanes (Calcif Tissue) in the last paragraph on col. 2, page 45 states, " As with the uptake of Ca 2+ from the external solution phase, the loss of entrapped P1 from the interior aqueous compartments of PS (+) and PS (-) liposomes was minimal in the absence of addedX-537 A". Since applicant is questioning the teachings of the prior art, the burden is therefore upon applicant to show that the entrapped antibiotic leaks out because the process is different and applicant has not

provided any experimental evidence to dispute the teachings of the prior art. Secondly, instant claims do not recite any specific amounts of the active agent encapsulated in the vesicles and how much should not leak out. Therefore, applicant's arguments that the inventor's declaration has met the burden of showing how the prior art process is different are not persuasive.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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